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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **Difenoconazole:** Addendum to Section 3 New Use Ecological Risk Assessment (DP 417610+) to Clarify Data Gaps

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Gregory Orrick 2015.11.19 17:57:00 -05'00'
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TO: Lindsay Roe, Risk Manager Reviewer
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At the request of the Registration Division, this addendum is to clarify that the list of data gaps noted in the recently completed ecological risk assessment in support of a variety of proposed uses and label amendments (DP 417610+, Dec. 19, 2014) is generic for all proposed and current difenoconazole uses with an outdoor exposure pathway and the identified studies are not requested to support only the proposed new uses and label amendments. The following are the data gaps that were identified in DP 417610+.

Given that exposure is expected and that difenoconazole is systemic, the following studies are now recommended based on the current guidance for pollinator risk assessment (USEPA, 2014).[1]

- Special study (OECD 213): Acute oral toxicity to adult honeybees – difenoconazole (TGAI)

- Special study: Chronic oral toxicity to adult honeybees – difenoconazole (TGAI)

1 USEPA, 2014. Guidance for Assessing Pesticide Risks to Bees. Environmental Fate and Effects Division, Office of Chemical Safety and Pollution Prevention.

- Special study: Chronic and acute toxicity to larval honeybees (acute value can be obtained simultaneously with chronic study) – difenoconazole (TGAI)

Several data gaps remain, as identified in past risk assessments (data unavailable or available data are insufficient). The impact of these data gaps on the risk conclusions varies with the use and application rate of difenoconazole.

- 850.2100 (Acute oral toxicity to birds) – CGA-142856 (*i.e.*, triazole acetic acid)[2]

- 850.4550 (Cyanobacteria toxicity) – difenoconazole (TGAI)

- 850.4100 (Terrestrial plant toxicity, seedling emergence) – TEP
  - The available Tier I study is supplemental because there were biologically significant effects observed in dicots at the limit test concentration which is below the maximum labeled single application rate (turf; 0.26 lb ai/A). The current risk assessment is impacted by the lack of a NOAEC for dicots. Tier II testing is required for the dicot species that showed effects in the available study (lettuce, soybean, and sugar beet). Furthermore, a NOAEC must be established at the maximum single application rate (Tier 1 test) for the other seven test species (those showing no effects in the available study) to meet the data requirement; alternatively, Tier II testing may be conducted for those species.

- 850.4150 (Terrestrial plant toxicity, vegetative vigor) – TEP
  - The available Tier I study is supplemental because the limit test concentration is below the maximum labeled single application rate (turf; 0.26 lb ai/A). The current risk assessment is not impacted. To meet the data requirement, a NOAEC must be established for all ten test species at the maximum single application rate (Tier I test). Alternatively, Tier II testing may be conducted.

- Chronic toxicity to benthic invertebrates (whole sediment: freshwater and estuarine/marine) – difenoconazole (TGAI)
  - There is uncertainty associated with chronic risk to benthic invertebrates given that pore water EECs are similar to water column EECs and a lack of acceptable toxicity data for benthic invertebrates. Although a sediment toxicity study (range finding with a freshwater midge) is available, the numerous deviations in the study limit its use for quantitative purposes. Data are recommended in part because the chronic LOC (1.0) is exceeded for aquatic invertebrates based on comparison of water column species toxicity data to pore water EECs. Sediment chronic toxicity testing with three species is recommended: freshwater midge, freshwater amphipod, and marine/estuarine amphipod.

In addition, submission of chronic toxicity data for 1,2,4-triazole, triazole acetic acid, and CGA-205375 may be useful for refining the risk concerns for birds, fish, and aquatic invertebrates.

2 This Guideline 850.2100 study on CGA-142856 has been submitted to EPA.